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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,160	08/09/2001	Sushma Pati	A-64580-4/RFT/RMS/AMS	4009

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,160

Applicant(s)

PATI ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 32-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

The preliminary amendment filed January 3, 2002 has been entered. Claim 1 has been cancelled.

Claims 32-71 have been newly added.

Accordingly, Claims 32-71 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 32-37, 41-52, and 60-69, drawn to a method of making a transgenic mammal comprising a modified endogenous nucleic acid, wherein the preselected target DNA sequence encodes an ion-channel protein, classified in class 800, subclass 21.
- II. Claims 32-37, 41-52, and 60-69, drawn to to a method of making a transgenic mammal comprising a modified endogenous nucleic acid, wherein the preselected target DNA sequence encodes a G-protein coupled receptor (GPCR), classified in class 800, subclass 21.
- III. Claims 32-37, 41-52, and 60-69, drawn to to a method of making a transgenic mammal comprising a modified endogenous nucleic acid, wherein the preselected target DNA sequence encodes an immunoglobulin, classified in class 800, subclass 21.
- IV. Claims 32-37, 41-52, and 60-69, drawn to to a method of making a transgenic mammal comprising a modified endogenous nucleic acid, wherein the preselected target DNA sequence encodes a growth factor, classified in class 800, subclass 21.
- V. Claims 32-37 and 41-70, drawn to to a method of making a transgenic mammal comprising a modified endogenous nucleic acid, wherein the preselected target DNA sequence encodes an enzyme, classified in class 800, subclass 21.
- VI. Claims 32-52, 60-69, and 71, drawn to to a method of making a transgenic mammal

comprising a modified endogenous nucleic acid, wherein the preselected target DNA sequence encodes a milk protein, classified in class 800, subclass 21.

Claim 32 links inventions I-VI. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim, claim 32. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are patentably distinct, one from the other, because the inventions are drawn to materially different methods that have different modes of operation, different functions, and different effects. The various methods of disrupting different genes to produce a transgenic mammal require different starting materials and the mammals produced by the methods have different uses based on their specific genetic modification and specific resultant phenotype. For example, the method of making a transgenic mammal having a modified ion-channel protein gene requires targeting polynucleotides that are specific to the gene being modified. A method of making a composition has use only if the product made has use. Thus, patentability hinges on the product made as well as the method. The methods of

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making a transgenic mammal having various endogenous genes modified are not obvious, one over the other. Thus, the methods of the inventions of Groups I-VI are patentably distinct, each from the other.

Each of the inventions of Groups I-VI requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, since patentability of a method of making a product is dependent on the use of the product made, the invention of Group I requires consideration of issues relating to the utility and enablement of a transgenic mammal having a modified ion-channel protein gene which is not required for examination of the invention of Group II. Furthermore, the searches for the inventions of Groups I-VI are not cointensive. Thus, search and examination of all 6 inventions in a single patent application constitutes a serious burden on the Examiner.

Where the claims recite an insertion sequence, Applicant is required to elect a species commensurate with the elected invention. This application contains claims directed to the following patentably distinct species of the claimed invention:

- polylinker sequence
- reporter gene
- human lysozyme gene
- human growth hormone gene
- human serum albumin gene
- human globin gene
- human immunoglobulin gene
- human enzyme gene
- any human gene under control of its endogenous promoter
- a modified endogenous regulatory element for an endogenous gene
- a transcriptional regulation cassette
- a dimerizing sequence
- hormone receptor gene
- viral receptor gene
- G-protein coupled receptor gene

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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Currently, Claims 32-42, 64, and 65 are generic with respect to the insertion sequence. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER